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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,833	12/27/2001	Todd A. Thompson	9345.7121-CON 4	9612

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EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/034,833	Applicant(s) THOMPSON ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9-16,18-22,51 and 60-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-16,18-22,51 and 60-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/14/05</u> | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 14, 2005 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1,3-6,8-16,18-22,51,60-68 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 defines the assembly as including components worn on the patient thereby including the patient as part of the claimed invention. The inclusion of a living being as part of the claimed invention renders the claim non-statutory.

Claim Objections

Claim 69 is objected to because of the following informalities: In claim 69, it is confusing to set forth an ECG device as a type of treatment device in that it is a diagnostic tool and performs no treatment. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3-6,9-16,18-22,51,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al ('070). Bond et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 42 adapted to be coupled to a generator 40 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, an anticoagulant, an antiplatelet, aspirin and a fibrinolytic drug such as tPA or streptokinase. Bond et al disclose that the ultrasound applicator 42 can be the one disclosed in US Patent No. 5,879,314 to Peterson et al which is incorporated by reference. The Peterson et al reference clearly sets forth the operating parameters as set forth in claim 1. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. Talish et al disclose an ultrasound treatment device having an assembly for positioning a transducer on the chest of a patient so that treatment can be provided without having an operator constantly hold the applicator. Talish et al disclose a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. The assembly includes a quick release mechanism as seen at the end of straps 20 in figure 1 and a quick release material as seen by the Velcro in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. Talish et al disclose in column 9 that various modifications may be made in the structural configuration of the placement module. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No.

5,556,372 which discloses use of a battery 32. It would have been obvious to one skilled in the art to have modified Bond et al such that it includes the assembly of Talish et al in order to provided means for stabilize placement of the applicator on the desired area without having an operator to continuously hold such. The use of hook and loop fasteners are old and well known and it would have been obvious to one skilled in the art to have replaced the clips with hook and loop fasteners. Such a modification merely involves the substitution of one well-known type of quick release mechanism for another. With regard to claims 5-6, the specific arrangement of the assembly used would have been an obvious design choice of known equivalents for providing placement of the transducer on the desired location in view of the Tallish et al disclosure referred to above. With regard to claims 15,16, Talish et al disclose means to releasably couple to transducer assembly to the electric generating means/battery. It would have been obvious to one skilled in the art to have further modified Bond et al such that it includes means to releasably couple to transducer assembly to the electric generating means in order to be able to easily change the battery if necessary.

Claims 60-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al as applied to claim 1 above, and further in view of Barsotti et al. Bond et al fails to specifically disclose the use of either or both continuous or pulsed wave ultrasound. Barsotti et al disclose that ultrasound therapy can be provided in either continuous wave mode or pulsed wave mode. Barsotti et al further disclose that various operating modes can be selected and varied depending upon the treatment desired. The modes can comprise different output power levels and are either pulsed or continuous wave ultrasound. In the absence of any showing of unexpected results the specific operating parameters selected would have been an obvious design choice without undue experimentation for achieving the desired effect. Therefore, it would have been obvious to one skilled in the art to have further modified Bond et al to includes means for varying the operating parameters as disclosed by Barsotti in order to allow one to change the conditions of the treatment provided.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bond et al in view of Talish et al as applied to claim 1 above, and further in view of Moehring et al and Berger et al. Moehring et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 128 adapted to be coupled to a generator 134 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, and a fibrinolytic drug such as tPA or streptokinase. Moehring et al disclose providing an image of the treatment site in order to properly locate the site prior to treatment. Berger et al disclose imaging of thrombi before treatment and the use of an EKG device to aid in triggering the image device. The use of an EKG trigger in an imaging system is old and well known means to eliminate motion artifacts. Therefore, it would have been obvious to one skilled in the art to have further modified Bond et al to include means for imaging the treatment site prior to treatment and an EKG device as a source of a trigger signal in order to properly locate the treatment site prior to treatment and eliminate motion induced artifacts from the image.

Claims 1,3-6,9-16,18,21,51,60-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al ('070). Moehring et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 128 adapted to be coupled to a generator 134 and an agent administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, and a fibrinolytic drug such as tPA or streptokinase. Moehring et al sets forth the operating parameters as set forth in claim 1. For example, Moehring et al discloses a power density of 50mWatts/cm^2 , a power output of a few milliwatts to a few watts (column 5) and a therapeutic frequency of 200KHz. The operating parameters are well known ultrasound therapy operating parameters for use on a patient without causing harm to the patient. Talish et al disclose an ultrasound treatment device having an assembly for positioning a transducer on the chest of a patient so that treatment can be provided without having an operator constantly hold the applicator. Talish et al disclose a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. The assembly includes a quick release mechanism as seen at

the end of straps 20 in figure 1 and a quick release material as seen by the Velcro in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. Talish et al disclose in column 9 that various modifications may be made in the structural configuration of the placement module. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. It would have been obvious to one skilled in the art to have modified Moehring et al such that it includes the assembly of Talish et al in order to provided means for stabilize placement of the applicator on the desired area without having an operator to continuously hold such. The use of hook and loop fasteners are old and well known and it would have been obvious to one skilled in the art to have replaced the clips with hook and loop fasteners. Such a modification merely involves the substitution of one well-known type of quick release mechanism for another. With regard to claims 5-6, the specific arrangement of the assembly used would have been an obvious design choice of known equivalents for providing placement of the transducer on the desired location in view of the Talish et al disclosure referred to above. With regard to claims 15,16, Talish et al disclose means to releasably couple to transducer assembly to the electric generating means/battery. It would have been obvious to one skilled in the art to have further modified Moehring et al such that it includes means to releasably couple to transducer assembly to the electric generating means in order to be able to easily change the battery if necessary. With respect to claims 60-67, Moehring et al disclose that the ultrasound therapy can be provided in either continuous wave mode or pulsed wave mode. The modes can comprise either pulsed or continuous wave ultrasound. In the absence of any showing of unexpected results the specific operating parameters selected would have been an obvious design choice without undue experimentation for achieving the desired effect.

Claims 19,20,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al as applied to claim 1 above, and further in view of Bond et al. Bond et al disclose a system for treating a thoracic cavity comprising an ultrasound applicator 42 adapted to be coupled to a generator 40 and an agent

administered to the patient to promote dissolution of thrombi. The agent can be a thrombolytic agent, an anticoagulant, an antiplatelet, aspirin and a fibrinolytic drug such as tPA or streptokinase. It would have been obvious to one skilled in the art to have further modified Moehring et al such that the agent is an anticoagulant, an antiplatelet, and aspirin. Such a modification merely involves the substitution of one type of agent used to promote dissolution of thrombi for another.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moehring et al in view of Talish et al as applied to claim 1 above, and further in view of Berger et al. Moehring et al disclose providing an image of the treatment site in order to properly locate the site prior to treatment. Berger et al disclose imaging of thrombi before treatment and the use of an EKG device to aid in triggering the image device. The use of an EKG trigger in an imaging system is old and well known means to eliminate motion artifacts. Therefore, it would have been obvious to one skilled in the art to have further modified Moehring et al to include an EKG device as a source of a trigger signal in order to properly locate the treatment site prior to treatment and eliminate motion induced artifacts from the image.

Response to Arguments

Applicant's arguments filed September 14, 2005 have been fully considered but they are not persuasive. Claim 1 positively sets forth the assembly as being worn on the chest of the patient, thereby including the patient as part of the claimed invention. Applicant should set forth that the assembly is "adapted" to be worn on the chest of the patient thereby clearly setting forth only the intended use of the device. The examiner does not agree with applicant's remarks regarding the placement module of Talish et al. The module shown would allow placement of other devices **above and below the module. The sides of the module define lateral sides of the module.** Furthermore, Talish et al disclose that various modifications can be made to the structural configuration of the placement module and any known attachment arrangement for positioning the transducer would have been obvious to one skilled in the art. Bond

refers to the Peterson et al patent (US Patent No. 5,879,314) which sets forth the operating parameters as claimed. The operating parameters set forth are well known parameters used in ultrasound therapy which will provide therapy without harming the patient. Talish is used as a teaching of an assembly for positioning an ultrasound assembly on the thoracic portion of a patient. The type of therapy provided does not preclude one from positioning any type of ultrasound therapy device on the chest using the device of Talish.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS